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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,545	08/29/2001	Lloyd Wolfsonbarger JR.	58772.000004	5273
7590	03/15/2005		EXAMINER	
JENKINS AND GILCHRIST 1445 ROSS AVENUE, SUITE 3200 DALLAS, TX 75202			COMSTOCK, DAVID C	
			ART UNIT	PAPER NUMBER
			3732	
DATE MAILED: 03/15/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/940,545	WOLFINBARGER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David Comstock	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 November 2004 and 07 January 2005.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 33 and 34 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                                |                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                           | Paper No(s)/Mail Date. _____.                                               |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>18 FEB 05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|                                                                                                                                                | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by Boyce et al. (5,899,939).

Boyce et al. disclose a monolithic bone implant, i.e. whole bone or a portion of whole bone, 20 that is contacted with a liquid organic agent, i.e. a type of polyethylene glycol, and freeze-dried, i.e. lyophilized (see col. 1, lines 6-17; col. 2, lines 9-15; col. 4, lines 20-24 and 45-46; col. 4, line 53-65; col. 5, lines 21-29; and col. 6, lines 8-13, 45-46 and 51-52. It is noted that providing layers and demineralizing the implant are both optional; therefore, the scope of the disclosure includes mineralized bone that is not provided with the layers (id.).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. (5,899,939) in view of Morse (5,333,626).

Boyce et al. disclose the claimed invention except for explicitly disclosing packaging of the implant. Morse discloses a similar invention that is packaged to preserve sterility and biologic potential in the implant and to avoid contamination and infection in the patient (see Fig. 1 and col. 1, lines 6-18; col. 2, lines 21-26; col. 3, lines 10-12, 21, 31-50, 57-61; col. 4, lines 8-12; col. 5, lines 57-65; col. 6, lines 5-25 and 43-46; and col. 7, lines 40-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the bone implant as disclosed by Boyce et al. with packaging, in view of Morse, in order to preserve sterility and biologic potential of the bone implant and to avoid contamination and infection in the patient. It would have been further obvious to provide the liquid organic agent in any of numerous ranges of amounts, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

***Response to Arguments***

Applicant's arguments filed 15 November 2004 and 07 January 2005 regarding Livesey et al. have been fully considered and are persuasive. Accordingly, the rejections relying on this reference have been withdrawn.

However, Applicant's arguments pertaining to Boyce are not persuasive.

In response to Applicant's argument that Boyce does not anticipate Applicant's invention, it is noted that all of the disclosures in a reference must be evaluated for what they fairly teach one of ordinary skill in the art. *In re Smith*, 32 CCPA 959, 148 F.2d 351, 65 USPQ 167; *In re Nehrenberg*, 47 CCPA 1159, 280 F.2d 161, 126 USPQ 383; *In re Watanabe*, 50 CCPA 1175, 315 F.2d 924, 137 USPQ 350. It is neither possible nor desirable to recite every possible permutation of an invention within a patent. That freeze-drying is only recited in one example does not mean that Boyce does not anticipate the invention as claimed. On the contrary, Boyce discloses many features that "the bone-derived implant of *this invention* can optionally possess" (see, e.g. col. 4, lines 22-23 and 53, emphasis added). In example 1, still referring to "this invention," Boyce continues to disclose that the bone, which has already been shown to explicitly include a liquid organic agent such as a polyethylene glycol, can be freeze-dried (see col. 6, lines 45-46 and 50-52). Thus, "this invention," i.e. the invention of Boyce, includes within its scope bone that is contacted with a liquid organic agent and freeze-dried.

In response to applicant's argument that Boyce fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e.,

unaltered collagen fiber orientation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, this does not in any way prove that Boyce does not have liquid organic material throughout the entire freeze-drying process, since Boyce does not even discuss fiber orientation. However, Boyce does explicitly say that the various substances, including the liquid organic material, “can be incorporated into the bone-derived implant of *this invention* or any of its constituent layers during *any* stage of the assembly of the implant,” which necessarily includes the stage wherein the bone is freeze-dried (col. 5, lines 24-28).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. Comstock  
07 March 2005

  
EDUARDO C. ROBERT  
PRIMARY EXAMINER